

GATES & COOPER
United States Patent Application
DECLARATION

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

MIXED BUFFER SYSTEM FOR STABILIZING POLYPEPTIDE FORMULATIONS

The specification of which:

- a. ☒ is attached hereto.
b. ☐ was filed on _____ as United States Application Number or PCT International Application Number _____ and was amended on _____ (if applicable), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT application having a filing date before that of the application on the basis of which priority is claimed:

- a. ☒ no such applications have been filed.
b. ☐ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
OTHER FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or 365(c) of any PCT international application(s) designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. PARENT APPLICATION OR PCT PARENT NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)
60/177,897	24 January 00

Please direct all correspondence in this case to the firm of Gates & Cooper at the address indicated below:

Customer No. 22462

GATES & COOPER
Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, CA 90045

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(1)	Full Name Of Inventor	Family Name VAN ANTWERP	First Given Name WILLIAM	Second Given Name PETER
	Residence & Citizenship	City Valencia	State or Foreign Country California	Country of Citizenship USA
	Post Office Address	Post Office Address 26833 Pinehurst Drive	City Valencia	State & Zip Code/Country California 91355 / USA
Signature of Inventor(1): <i>W Van Antwerp</i>				Date: <i>11/28/00</i>
(2)	Full Name Of Inventor	Family Name GULATI	First Given Name POONAM	Second Given Name S.
	Residence & Citizenship	City La Canada	State or Foreign Country California	Country of Citizenship USA
	Post Office Address	Post Office Address 5467 La Forest Drive	City La Canada	State & Zip Code/Country California 91011 / USA
Signature of Inventor(2): <i>T Gulati</i>				Date: <i>11/28/00</i>

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) it refutes, or is inconsistent with, a position the applicant takes in:
 - (i) opposing an argument of unpatentability relied on by the Office, or
 - (ii) asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application:
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

Attorney Docket No.: 130.9-US-U1

Applicant(s): William P. Van Antwerp and Poonam S. Gulati
Serial No.: Not yet assigned
Filed: Herewith
For: MIXED BUFFER SYSTEM FOR STABILIZING POLYPEPTIDE
FORMULATIONS
Group: Not yet assigned
Examiner: Not yet assigned

**POWER OF ATTORNEY BY ASSIGNEE
AND EXCLUSION OF INVENTOR(S) UNDER 37 C.F.R. 3.71**

Dear Sir:

The undersigned assignee of the entire interest in the above-identified subject application hereby appoints

George H. Gates
Victor G. Cooper
Karen S. Canady
William J. Wood
Jason S. Feldmar
Paul H. Kovelman

Registration No. 33,500
Registration No. 39,641
Registration No. 39,927
Registration No. 42,236
Registration No. 39,187
Registration No. 35,228

as its attorney to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith, said appointment to be to the exclusion of the inventors and their attorney(s) in accordance with the provisions of 37 C.F.R. 3.71.

An assignment of the entire interest in the above-identified subject application:

- ☐ was recorded on _____ at reel/frame _____ / _____.
☒ is submitted herewith for recording.

Please direct all telephone calls to William J. Wood at (310) 641-8797 and all correspondence relative to said application to the following address:

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